K062267

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510(k) Summary

acc. to 807.92

OCT 3 1 2006

Submitter's Name and Address:

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The Netherlands

Contact Person:

Mr. Hans Venings
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Applicants US Contact Person:

Mr. Bryan Overton
Regulatory Affairs

Phone: (215) 721-5400
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Date submission was prepared: 2006-07-31

Device Name:

Common Name:	Ventilator
Classification Name:	Ventilator, Continuous
Regulation Number:	21 CRF 868.5895
Class:	II

Legally Marketed Device Identification: Oxylog 3000

Device Description:

The Oxylog 3000 is a time-cycled, volume-constant and pressure controlled emergency and transport ventilator for patients with a tidal volume from 50 mL upwards. The device is intended for use by trained healthcare professionals, i.e. doctors, nurses, technicians, respiratory therapists, paramedics.

The device is intended for mobile use for emergency medical care or primary care of emergency patients:

- During transport in emergency rescue vehicles or aircrafts including helicopters
- In accident and emergency departments, in the recovery room.

Mobile use for secondary transfers:

- During transfer by road or air
- When moving ventilated patients around in the hospital.

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Predicate Devices:

510(k) Number	Device Name
K984577	Oxylog 2000
K040790	LTV 1000
K003068	Savina
K942938	Crossvent-4
K042468	iVent 201
K042607	Primus US

Substantial Equivalence:

The Oxylog 3000 is found similar to the Oxylog 2000 (K984577) and the transport features of the LTV 1000 (K040790).

The Oxylog 3000 incorporates a Pressure Controlled Ventilation plus mode and a Pressure Support mode identical to the Savina ventilator (K003068). Furthermore, the Oxylog 3000 uses the same operating principle as the Savina.

Specific features and setting ranges of the Oxylog 3000 are found similar to those features on the Crossvent-4 ventilator (K942938) and the iVent 201 ventilator (K042468).

The accessories of the Oxylog 3000 are similar to the accessories of the LTV 1000 (K040790) and the accessories of the Primus US (k042607).

Summary of Performance Testing:

Safety testing was conducted per IEC60601-1, IEC60601-1-2 and other applicable standards with respect to mechanical, electrical and biocompatibility.

The results of all verification and validation testing demonstrate that all system and design requirements for the Oxylog 3000 device have been met.

Qualification included hazard analysis, system level qualification and verification / validation tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dräger Medical B.V.
C/O Mr. Bryan Overton
Regulatory Affairs
Dräger Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

OCT 3 1 2006

Re: K062267
Trade/Device Name: Oxylog 3000
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: July 31, 2006
Received: August 4, 2006

Dear Mr. Overton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

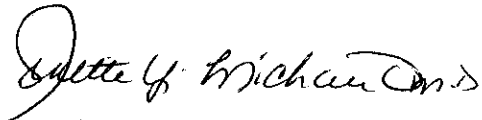
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): _____

Device Name: **Oxylog 3000**

Indications for Use:

Oxylog 3000 is a time-cycled, volume-constant and pressure controlled emergency and transport ventilator for patients with a tidal volume from 50 mL upwards.

Prescription Use _√_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Sign-Off)
...ion of Anesthesiology, General Hospital,
...tion Control, Dental Devices
...Number: K062267